

# **EXHIBIT D**

**KFX.003RX**

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant	:	Michael L. Green, et al.
Reexam. No.	:	90/011430
Filed	:	January 11, 2011
For	:	SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE
Examiner	:	Jeanne Marie Clark
Art Unit	:	3993
Conf. No.	:	1162

**PETITION UNDER 37 C.F.R. § 1.182**

**Mail Stop Petition**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to M.P.E.P. § 2287.01, Patentee respectfully submits this Petition under 37 C.F.R. § 1.182 to have the Examiner consider the accompanying Information Disclosure Statement in the above-referenced reexamination proceeding. This Information Disclosure Statement was previously filed on April 12, 2011, a date which was within two-months from the date of the Order Granting the Request for Ex Parte Reexamination, which issued on February 16, 2011.

A Notice of Intent to Issue Ex Parte Reexamination Certificate was issued by the Examiner on March 28, 2011. In a telephone conference with the Examiner, the undersigned was informed that the Information Disclosure Statement filed on April 12, 2011 would not be considered without a granted petition under 35 C.F.R. § 1.182. Accordingly, the Patentee is hereby re-submitting the Information Disclosure Statement with this petition.

Patentee respectfully submits that the initial Information Disclosure Statement filed on April 12, 2011 was timely because it was filed "within two (2) months of the date of the order for

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**Application No.:** 90/011430  
**Filing Date:** January 11, 2011

reexamination" pursuant to 37 C.F.R. § 1.555(a). Thus, Patentee was in full compliance with the Rules regarding the timing for filing an Information Disclosure Statement in a reexamination proceeding. Accordingly, Patentee respectfully submits that the present petition should be granted. To hold otherwise would render Rule 1.555(a) ineffective and meaningless. Patentee should not be punished for relying in good faith on the plain language of the Code of Federal Regulations.


Patentee respectfully submits that the information submitted with the accompanying Information Disclosure Statement does not render any claim unpatentable. Nonetheless, Patentee submits that consideration of this information by the Examiner is appropriate. The M.P.E.P. advises that applicants should submit information "even though they may not be required to do so, to strengthen the patent and avoid the risks of an incorrect judgment on their part on materiality or that it may be held that there was an intent to deceive the Office." M.P.E.P. § 2001.05. Accordingly, Patentee believes it appropriate for the Examiner to make an independent determination regarding the materiality of the submitted information.

This Petition is being submitted with the fee as set forth in 37 C.F.R. 1.17(f) for a petition under 37 C.F.R. 1.182. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

**KNOBBE, MARTENS, OLSON & BEAR, LLP**

Dated: April 28, 2011

By:   
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Ryan E. Melnick  
Registration No. 58,621  
Attorney of Record  
Customer No. 20,995  
(858) 836-9000

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Docket No.: **KFX.003RX**

**Customer No. 20995**

**INFORMATION DISCLOSURE STATEMENT**

Applicant	: Michael L. Green, et al.
Reexam. No.	: 90/011430
Filed	: January 11, 2011
For	: SYSTEM AND METHOD FOR ATTACHING SOFT TISSUE TO BONE
Examiner	: Clark, Jeanne Marie
Art Unit	: 3993
Conf. No.	: 1162

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified re-examination is a PTO/SB/08 Equivalent listing 3 references, of which 3 are enclosed/submitted.

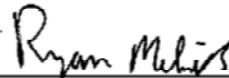
This Information Disclosure Statement is accompanied by a Petition under 37 C.F.R. § 1.182. This Information Disclosure Statement is identical to the one filed on April 12, 2011, which was filed "within two (2) months of the date of the order for reexamination" pursuant to 37 C.F.R. § 1.555. No fee is required. Nonetheless, if the Patent Office determines that a fee is required, the Commissioner is authorized to charge any such required fees to Deposit Account No. 11-1410.

Enclosed and listed on the PTO/SB/08 is a Statement of Tate Scott. If the Examiner requires any further information regarding the contents this statement, she is invited to contact the undersigned or request such information pursuant to 37 C.F.R. § 1.105.

**Application No.:** 90/011430  
**Filing Date:** January 11, 2011

Respectfully submitted,  
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: April 28, 2011

By:   
Ryan E. Melnick  
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PTO/SB/08 Equivalent

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Application No.	90/011430
	Filing Date	January 11, 2011
	First Named Inventor	Michael L. Green, et al.
	Art Unit	3993
(Multiple sheets used when necessary)	Examiner	Clark, Jeanne Marie
SHEET 1 OF 1	Attorney Docket No.	KFX.003RX

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>1</sup>

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	1	Mazzocca et al., "Arthroscopic Single-Row Versus Double-Row Suture Anchor Rotator Cuff Repair," <i>The American Journal of Sports Medicine</i> , 33:1861 (2005).	
	2	Mazzocca et al., Arthroscopic Single versus Double Row Suture Anchor Rotator Cuff Repair, abstract of presentation made on June 25, 2004 at 2004 Annual Meeting of the American Orthopaedic Society for Sports Medicine in Quebec, Canada, publication date unknown.	
	3	Statement of Tate Scott, dated April 12, 2011.	

11016104/adk/040611

Examiner Signature	Date Considered
<p>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

## **Arthroscopic Single versus Double Row Suture Anchor Rotator Cuff Repair**

### **Authors:**

Augustus D. Mazzocca MD, Peter J. Millett MD, Stephen A. Santangelo, Robert A. Arciero MD, (Farmington, CT; Boston, MA)

### **Objective:**

Maximizing mechanical and biologic healing potential while minimizing surgical morbidity is the goal of arthroscopic rotator cuff repair (ARCR). The purpose of this study was to evaluate four ARCR techniques. The hypothesis is that a double row anchor repair is superior to a single row repair.

### **Methods:**

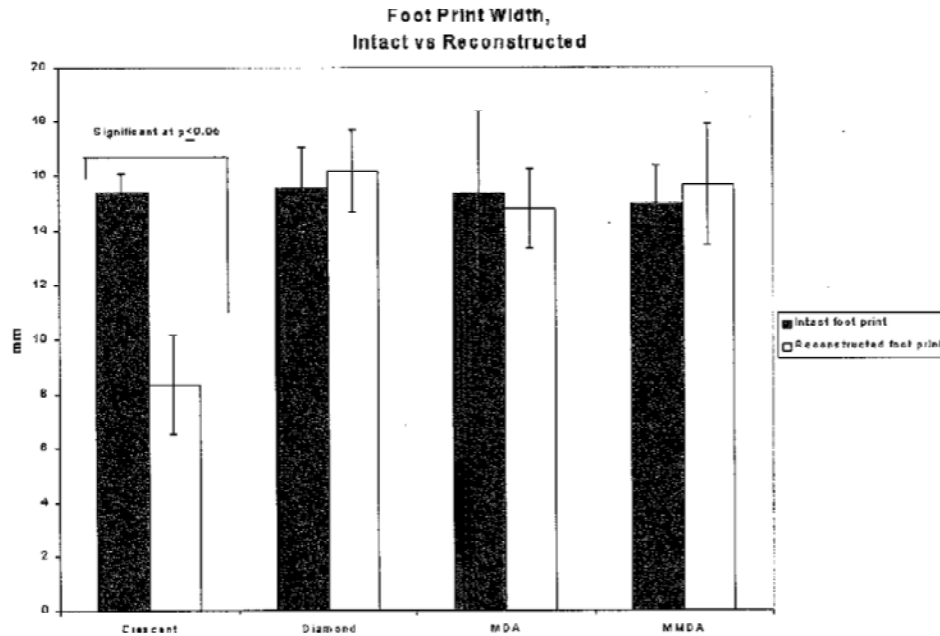
Twenty (10 male; 10 female) fresh frozen cadaver shoulders (Mean age 76.3+13.4) were randomly assigned to four repair techniques (Crescent(C), Diamond (D), Mattress Double Anchor (MDA), and Modified Mattress Double Anchor (MMDA)). Angle of pull(135 degrees), anchor type, Bone mineral density(BMD), anchor distribution, angle of anchor insertion, arthroscopic technique, suture type and suture size were all controlled. The number of arthroscopic instrument passes through the tendon was recorded. Tendon length and width was quantified pre and post repair. Displacement of the repaired tendon to bone with repetitive submaximal cyclic load (3000 cycles at 1 Hz with 100 N) was quantified. Load to failure was assessed at 31mm/min after cyclic loading. A gap formation greater than 4mm and a load to failure less than 250N was considered a biomechanical failure.

### **Results:**

There were no differences between the groups for age, sex, or bone mineral density. There was a significant  $P<0.05$  greater supraspinatus footprint width and less suture passes through tendon with the double row than single row technique. There was no evidence for large effect size differences in repetitive submaximal cyclic loading or load to failure (Cohens distribution =0.8) All groups demonstrated significantly ( $p<0.05$ ) less displacement when compared to a standard 4mm gap formation. All groups demonstrated significantly greater load to failure than the standard 250 N. 2/20 samples demonstrated anchor pull out and 18/20 failed with suture pulling through the tendon.



(cont.)

**Arthroscopic Single versus Double Row Suture Anchor Rotator Cuff Repair****Conclusions:**

All groups demonstrated superior biomechanical properties when compared to previously reported population limits. There was no difference in cyclic load or load to failure between any of the groups. The double row anchor repair had less passes through the tissue, equal mechanical properties, and a consistently larger footprint which may aide in biologic healing.



# The American Journal of Sports Medicine

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## **Arthroscopic Single-Row Versus Double-Row Suture Anchor Rotator Cuff Repair**

Augustus D. Mazzocca, Peter J. Millett, Carlos A. Guanche, Stephen A. Santangelo and Robert A. Arciero

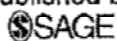
*Am J Sports Med* 2005 33: 1861

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# Arthroscopic Single-Row Versus Double-Row Suture Anchor Rotator Cuff Repair

Augustus D. Mazzocca,<sup>\*†</sup> MD, Peter J. Millett,<sup>‡</sup> MD, Carlos A. Guanche,<sup>§</sup> MD, Stephen A. Santangelo,<sup>†</sup> and Robert A. Arciero,<sup>†</sup> MD

From the <sup>†</sup>Department of Orthopaedic Surgery, University of Connecticut Health Center, Farmington, Connecticut, <sup>‡</sup>Harvard Shoulder Service, Brigham and Women's Hospital, Boston, Massachusetts, and the <sup>§</sup>Southern California Orthopaedic Institute, Van Nuys, California

**Background:** Recurrent defects after open and arthroscopic rotator cuff repair are common. Double-row repair techniques may improve initial fixation and quality of rotator cuff repair.

**Purpose:** To evaluate the load to failure, cyclic displacement, and anatomical footprint of 4 arthroscopic rotator cuff repair techniques.

**Hypothesis:** Double-row suture anchor repair would have superior structural properties and would create a larger footprint compared to single-row repair.

**Study Design:** Controlled laboratory study.

**Methods:** Twenty fresh-frozen cadaveric shoulders were randomly assigned to 4 arthroscopic repair techniques. The repair was performed as either a single-row technique or 1 of 3 double-row techniques: diamond, mattress double anchor, or modified mattress double anchor. Angle of loading, anchor type, bone mineral density, anchor distribution, angle of anchor insertion, arthroscopic technique, and suture type and size were all controlled. Footprint length and width were quantified before and after repair. Displacement with cyclic loading and load to failure were determined.

**Results:** There were no differences in load to failure and displacement with cyclic loading between the single-row repair and each double-row repair. All repair groups demonstrated load to failure greater than 250 N. A significantly greater supraspinatus footprint width was seen with double-row techniques compared to single-row repair.

**Conclusions:** The single-row repair technique was similar to the double-row techniques in load to failure, cyclic displacement, and gap formation. The double-row anchor repairs consistently restored a larger footprint than did the single-row method.

**Clinical Relevance:** The arthroscopic techniques studied have strong structural properties that approached the reported performance of open repair techniques. Double-row techniques provide a larger footprint width; although not addressed by this study, such a factor may improve the biological quality of repair.

**Keywords:** rotator cuff; shoulder; biomechanics; arthroscopy

In the past decade, arthroscopic repair has become a well-established surgical technique for the treatment of complete rotator cuff tears. Clinical results have been extremely satisfactory in managing small, medium, large, and massive rotator cuff tears.<sup>2,6,11,14,18,19,21,22</sup> Long-term follow-up evaluations have revealed that excellent clinical

outcomes can be maintained.<sup>11,14,21,22</sup> A recent retrospective study comparing arthroscopic to mini-open rotator cuff repairs demonstrated comparable outcome results, with a decreased incidence of fibrous ankylosis and a trend for improved motion with the arthroscopic technique.<sup>18</sup>

Despite these apparent favorable reports, recurrent tears after open and arthroscopic rotator cuff repair remains one of the most common complications. A review of studies examining rotator cuff integrity after open surgery has demonstrated that the retear rate can be more than 50%.<sup>7,10</sup> Interestingly, recurrent defects after open rotator cuff repair have not correlated with clinical outcome. However, shoulders with intact repairs do appear to have substantially better functional results than those with recurrent tears.<sup>7,8,10,16</sup> A study on repair integrity

\*Address correspondence to Augustus D. Mazzocca, MD, Department of Orthopaedic Surgery, University of Connecticut, 10 Talcott Notch Road, Farmington, CT 06034 (e-mail: admazzocca@yahoo.com).

One or more of the authors has declared a potential conflict of interest as specified in the AJSM Conflict of Interest statement.

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